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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,323	03/11/2004	Jessica G. Chiu	5618P3784	1769

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EXAMINER

SHELL, LAURA C

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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01/10/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/800,323

Applicant(s)

CHIU ET AL.

Examiner

Laura C. Schell

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2007.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61-68 and 79-83 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61-68 and 79-83 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/25/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 61, 63, 68, 79, 80 and 82 are rejected under 35 U.S.C. 102(b) as being anticipated by Davis (US Patent No. 6,045,531). Davis discloses a method comprising: advancing a cannula percutaneously through a blood vessel to a region of interest (Figs. 4-6, the cannula enters the vessel at 30), the cannula having a proximal end (Figs. 5 and 6, near connection to 62), a distal end (near 106), and an exterior surface (103) at or adjacent the distal end of the cannula axially coupled to a balloon (114), inflating the balloon from a first diameter to a different second diameter that is at least equivalent to An inner diameter of a blood vessel to occlude the blood vessel at the region of interest (Figs. 4-6 and the abstract disclose that the balloon is inflated to a second diameter to occlude the vessel at the region of interest); infusing a treatment agent to the region of interest distal to the balloon (col. 7, lines 21-25 disclose that lumen 136 delivers a treatment agent to openings 106 which are distal to the balloon); perfusing a blood flow between a location in the blood vessel proximal to the balloon and the region of interest distal to the balloon (col. 7, lines 45-50 disclose that blood perfuses between both sides of the balloon via openings 110 and 104).

In reference to claim 63, Davis discloses that inflating includes inflating the balloon for a first period of time and perfusing includes deflating the balloon for a second period of time; and at least one more repetition of inflating, infusing, and deflating (col. 7, line 40 through col. 8, line 51).

In reference to claim 68, Davis discloses that inflating includes: increasing an axial length of the balloon (Figs. 5 and 6); and maintaining the inflation pressure on the inner diameter of the blood vessel (col. 7, lines 39-45).

In reference to claim 79, Davis discloses that perfusing comprises perfusing the blood vessel coupled by human vasculature to a beating heart (col. 2, lines 25-26).

In reference to claim 80, Davis discloses that perfusing comprises perfusing the blood vessel coupled by human vasculature to a beating heart (col. 2, lines 25-26).

In reference to claim 82, Davis discloses that perfusing comprises perfusing a blood flow from a location in the blood vessel proximal to the balloon, to a location in the region of interest distal to the balloon (col. 7, lines 45-50 disclose that blood perfuses between both sides of the balloon via openings 110 and 104).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 62 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis (US Patent No. 6,045,531) in view of Peacock et al. (US 2002/0049402). Davis discloses the device substantially as claimed including perfusing blood from a location proximal the balloon (via 110) to a location distal the balloon (104), however Davis does not disclose that the location distal to the balloon is a hole through the exterior surface of the cannula. Peacock, however, discloses using holes through the exterior surface of the cannula (Figs. 1a and 1b, holes 4 and 5) for perfusion on either side of the occluding element. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Davis to include holes on the distal end/side of the balloon for perfusion, as taught by Peacock, in order to enhance perfusion and blood flow.

Claims 64-66 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis (US Patent No. 6,045,531) in view of Sahota (US Patent No. 5,370,617). Davis discloses the method substantially as claimed except for the guidewire and retraction of the guidewire through the guidewire lumen. Sahota, however, discloses a

perfusion catheter (Figs. 1 and 4, with a balloon (12) and perfusion holes on the exterior of the catheter (54 and 56) proximal and distal to the balloon. Sahota, further discloses a guidewire lumen (57) with a guidewire (16) and also discloses retracting back the guidewire disposed through the guidewire lumen extending from the proximal end of the distal end of the cannula and exiting an opening in the cannula distal to a balloon, for a first period of time (col. 3, lines 21-37), as well as that the retracting includes retracting a distal end of the guidewire from a location distal to at least one hole from the guidewire lumen through the exterior surface of the cannula and proximal to the balloon to a location proximal to the at least one hole (col. 3, lines 21-37). Sahota further discloses advancing the guidewire to a location distal to the at least one hole to prohibit blood perfusion between a location in the blood vessel proximal to the balloon and the region of interest, for a second period of time, and repeating infusing, retracting and advancing at least once more (Figs. 4-8). Sahota also discloses retracting a distal end of the guidewire to control an amount of blood perfusion between a location in the blood vessel proximal to the balloon and the region of interest by adjusting the guidewire to extend or retract a distal end of the guidewire to a location amongst a plurality of the at least one hole to allow blood to perfuse between the holes and the lumen at a selected perfusion rate (Figs. 4-8). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Davis with the guidewire, as taught by Sahota, in order to provide a method which advantageously uses already present elements within the device to better perform and control the medical procedure.

Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Davis (US Patent No. 6,045,531) in view of Alt (US Patent No. 6,805,860). Davis discloses the method substantially as claimed except for the infusing of progenitor cells. Alt, however, discloses a method of infusing progenitor cells (Fig. 1 and col. 13, lines 27- 31). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Davis with the step of infusing progenitor cells, as taught by Alt, in order to provide a method of treating a wider spectrum of diseases.

Response to Arguments

Applicant's arguments with respect to claims 61-68 and 79-83 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

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